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1.0 Executive Overview
1.1 Executive Summary: The new (not-so) normal

There is a lot of talk these days about “the new normal.” We could see the expression as the catch-phrase equivalent of throwing up our arms and surrendering to a new set of rules and realities that we may not like but we have to work with anyway. Most of the “new normal” talk echoes off of Washington politics, where the new normal is a rebranding of chaos as the like-it-or-not expected order of affairs, but in the supplement industry it means something different.

For companies in the nutrition industry, the “new normal” may be very different, less desperate, less exasperating, more hopeful. For us, the new normal could include the $41.1 billion in sales on 6 percent growth NBJ estimates for 2016. This is a notch up from 5.9 percent in 2015, suggesting the industry has settled in to what feels like a modest pace, after recovering from the historic slowdown in 2014 (when the industry, reeling from a spate of negative headlines, slowed to 5.1 percent from 7.5 percent the year before).

So “the new normal” starts to sound like the good times are over but the industry has found its footing. Omega 3s, a major target of the negative headlines circa 2013, have crawled out of negative growth to increasing sales that suggest a turnaround. While 1.9 percent might not sound like a lot in the supplement world, it’s a vast improvement over the negative 0.5 percent in 2015 or the plunge to negative 5.4 percent in 2013.

The new normal is sounding better all the time.

The NBJ Supplement Business Report is the guide to that new normal—the numbers and the nuance, the qualitative and the quantitative squeezed into 378 pages with 123 charts and commentary from the most thoughtful voices in the industry.

Those voices, and their perspectives, are more important than ever.

Among the reasons those perspectives, and the numbers to back them up, are so important is that the new normal for supplements does include some shadow of Washington drama. The new normal there, of course, is that there is no normal and at press time, that seems to grow more apparent by the hour in a news cycle measured in minutes. In February’s NBJ Dark Issue, we wrote of a “post-regulatory” age with the Trump administration telegraphing a business-friendly era of less enforcement and fewer regulations and ominous actions like the New Dietary Ingredient guidance being sidelined indefinitely. Back in February, the debate was about how the industry should react—there was almost a certainty to the uncertainty. The game now seems more about who is going to be in charge than what they are going to do. That game only starts in the oval office. The ice is thin in the nation's capital this spring. With supplement champion Jason Chaffetz announcing in April that he wouldn’t seek a second term, and a month later telling constituents he'd leave Capitol Hill at the end of June, the whole structure of political allies in Congress gets thrown into question. Trade groups thought they had time to find a replacement to head the House contingent of the Dietary Supplement Caucus, but timetables can spin like a turntable these days.

Welcome to the new normal.

The question becomes what to do with steady growth and the possibility that the spotlight will be trained on Washington indefinitely (does the New York Times have room on the front page for anything that doesn't include at least one Trump family member?). Collaboration becomes the obvious answer. It’s been the answer since early 2015, when the New York attorney general’s herbal supplement grandstanding threw the industry into a handwringing fit. Following that media pummeling, trade groups began working together and major retailers stepped up their gatekeeper game. In reality, it’s too early to attribute the steadier growth to those efforts. Much of the recovery is more likely based in the public’s short
attention span than the positive steps the industry has taken. The worst year, 2014, was driven by headlines questioning efficacy and not charging fraud. When publicity-hungry Dr. Paul Offit was angling for media mentions and the Annals of Internal Medicine brought their vitamins-are-worthless tag team act into the ring, the punch was felt in all corners. But the study-of-the-week shrug could make the industry increasingly immune to sideshows such as theirs.

So industry reform that takes fraud out of the equation—and a public ready to shrug off sideline shots at efficacy, as surveys suggest—could bring the industry back to a place that’s less about crisis and more about confidence in the business plan. Today, success in the supplement industry is less about reading tea leaves and hedging against external events and more about following trends—seeing where competitors are winning so you can win there too. There may not be agreement about a level playing field, but you can at least see the goal posts now. The smoke, most of it, has cleared.

But to win on that field, you need a playbook. We recommend the NBJ Supplement Business Report.

In this year’s report, you will see growth across categories and channels. Look at the big numbers to get a sense of where the wind is blowing and then dip into sales ingredient-by-ingredient to see where the air is still or swirling.

We’ve also switched out the lens on company profiles. We still feature the major players—but don’t expect a hierarchical list by sales. In a dynamic market where the right product, pitch and channel choreography can take companies and whole categories from bit-part to major player in a matter of months, we’ve decided the profiles need to include the smaller companies that are carving out new kinds of success and defining markets in ways that even the biggest companies should

The U.S. nutrition industry is expected to reach $294.1 billion in sales by 2021, with a 10-year CAGR of 8.7%. This strong growth is due to ever-increasing consumer demand and awareness, as well as increasing accessibility of natural and organic brands.
1.2 The lure of the third rail

Risky categories like weight loss, sexual health, and cognition also ripe with opportunity

Ask an aging Gen X-er or Baby Boomer what they’d most like to improve about their health, and you’ll probably get a wish list that goes something like this: Lose 10 pounds. Stop forgetting where I left my keys. Have more sex (or, specifically, more sex drive).

Studies show six in 10 adults weigh more than they want to. More than 13 percent of those age 45 or older report “worsening confusion or memory loss.” 39 percent of women lack sex drive, and 18 percent of men suffer from erectile dysfunction. Consumers are clamoring for solutions but, thus far, the pharmaceutical industry is striking out: A long list of dementia/Alzheimer’s drugs have failed to show significant benefit in clinical trials. The half-dozen weight-loss drugs on the market come with brutal side effects. And the “female Viagra”, Addyi, approved in August, has suffered embarrassingly low sales due to warnings that if women take it with alcohol they might pass out.

To dietary supplement makers, all this —albeit depressing—illustrates a wealth of untapped market potential. Even in a period of relatively flat growth for the overall market, sales of weight loss, cognitive health, and sexual health products are all growing, representing more than $3.5 billion in sales in 2015, according to NBJ. But while consumer demand and lack of innovation is tempting more upstanding companies to wade into these categories, those interested in following their lead should take heed: They are also among the least trusted categories by consumers (for good reason), and the most scrutinized by regulators.

“The market potential is great,” says science and regulatory affairs consultant Risa Schulman, PhD, of Tap Root. “But some of these categories have been abused for so long by unscrupulous companies making egregious claims or adulterating products. You really have to be buttoned-up on your science and willing to tone down your claims if you want to succeed.”
Lack of trust

Survey the long saga of scandal in the dietary supplement industry and weight-loss and sexual enhancement products play a starring role:

In 2004, the Food and Drug Administration banned products containing ephedra after widespread reports that it led to heart attacks and deaths. Four years later, FDA warned consumers to stop using Hydroxycut, after an investigation found it led to liver problems. In 2009, FDA warned that it had found 72 weight loss products which included “active pharmaceutical ingredients.” And in 2013, the agency extended a similar warning about sexual enhancement supplements, after finding 23 products, with names like Mojo Nights, Rock-it Man, and Stiff-it, contained the very erectile dysfunction drug—Viagra—they claimed to replace.

The trend continues today. Of the 80 warning letters issued by FDA to supplement companies in 2015, at least 29 went to diet-pill makers, mostly for peddling products that the agency either considers to be “new dietary ingredients” or not dietary ingredients at all (frequent targets included the stimulant BMPEA, a.k.a. Acacia rigidula, and the stimulant pycnogenol, which is sold as a drug in Russia)

Of the 23 products called out in the first half of 2016 for being “tainted products marketed as dietary supplements,” 15 were sexual enhancement supplements and the rest were weight loss products.

Forty-year industry veteran Anthony Almada says the reason these categories tend to be a magnet for malfeasance is simple: unlike with “experientially inert” products like multi-vitamins, which take a while to have a tangible impact if they
have one at all, consumers expect to either look different or feel different fast when they take a diet pill or sexual enhancement product. If that doesn’t happen, they move on to the next shiny new thing.

“When you are selling things that are supposed to impact the way you look or feel, you tend to enter into a slippery slope,” he says. “There is this underbelly of industry players who know the only way they can produce a repeat buy is if the consumer takes their product with the derivative of a real drug.” In other cases, such as with ephedra, the supplement really does work, but in doing so presents problematic side-effects.

Head games
The nascent field of cognitive health supplements has caught the eye of regulators more recently for very different reasons. The target population is often the elderly, and considered vulnerable. “People looking online for cures or treatments for Alzheimer’s disease and dementia are at their most desperate, and it’s clear from what we’ve found that many of these products prey on that desperation,” said U.S. Senator Claire McCaskill in June, calling for an FDA crackdown.

Even for upstanding supplement companies who set out to do the right thing and develop good science behind their claims, Schulman says it can be exceedingly difficult to design a study that shows demonstrable, significant impacts on memory in a healthy population (under DSHEA, supplements can’t claim to address dementia or Alzheimer’s anyway, so studying those populations is unwise). Even when a population does show memory improvement, companies must be painstakingly clear in their claims to talk about what kind of memory they improve. (As DSM learned in 2014 when the FTC made it change its labels on its brain health products).

Put simply, cognitive health is a regulatory mine field.

How smart companies can do it right
Schulman says that, as a general rule, few companies in the United States are interested in touching the male sexual health category. “I think people are staying away from all aspects of it right now. If you just look at the shelves, it’s not out there.”

But she and others say they have seen a big uptick in interest in the weight loss category, after a period when it was deliberately avoided by reputable companies. “I see companies that are very interested in going into this area. They are looking toward branded ingredients, and they are being very careful about how they design their research and what they say about it,” says Schulman.

Barbara Davis, of ingredient company PLT Health Solutions, agrees.

“Over the past few years it didn’t seem like there was, from a supplement perspective, much interest in new product development. But for about the past year, we are hearing more of our customers talking about how they are doing new products and reformulating their products to focus on weight management.”

In May, PLT rolled out a new, branded, botanical ingredient, SlimVance, after five years of research showing its combined ingredients work synergistically to inhibit fat cell accumulation and promote the breakdown of fat cells. As part of their process, they surveyed brands on what they look for in an ingredient and got some surprisingly detailed responses:

“Obviously, everyone wants randomized-controlled trials behind their claims, but it goes deeper than that,” she says. Brand-holders and manufacturers want to see multiple, independent studies, conducted by separate investigators at separate universities or research organizations, “so it is not the same people conducting all the research.” They want studies involving men and women. They want mildly overweight participants, rather than obese ones. They want big sample sizes. And when it comes time to make a claim, they want to be able to say not just that the ingredient will help people lose weight but precisely how. Does it make you feel fuller? Increase energy expenditure? Block fat absorption or decrease maturation of fat cells? And where is the science that says so?
“It just won’t work anymore to do a quick, down and dirty study, showing a little bit of weight loss in a few obese people,” Davis says.

Their latest study, a multi-center RCT involving 130 people over 16 weeks, showed an average of 12 pounds of weight loss after four months (Impressive, but not exactly fodder for a late-night infomercial).

That’s OK, Davis says. In order to climb out of the shadows, the new generation of weight loss products needs to take things slower, and stress that diet and exercise matter too. “We as an industry need to communicate that there is no magic bullet.”

Specific solutions
Uber-specific claims backed by rock-solid science are also critical for gaining trust of brands and consumers in the cognitive health field, says Brenda Fonseca, technical services manager for cognition and innovation at Kemin Industries. The company spent nearly $4.5 million to develop and research its new cognitive health product, Neumentix, and plans to post detailed mechanism of action videos, and full texts of its studies on its consumer-facing website. “More specific claims are definitely appealing right now—not just saying this will improve your memory but what type of memory and how.”

In the mine-field that is the sexual health supplement market, a Canadian pedigree—where pre-market approval of supplements is required—may be an asset, says Shawna Page, founder of femMED. Founded in 2007, the company makes a broad line of women’s health products, including a libido booster, and also a sexual enhancement product for men. They are among the company’s top-sellers, available in mass retailers in Canada. But in recent years, customers from the United States, the Middle East, China, and elsewhere have been buying more and more online.

“One of the single biggest reasons these customers come to us is because we are Canadian,” says Page, noting that it took three years and required countless back-and-forth with regulators before she could start selling her libido formula. “Those in the know and in the industry recognize and appreciate the rigor we have to go through in order to sell our products in Canada.” Her advice to U.S. companies: “If money is no object, hire one of the regulatory companies here in Canada (to help you design your study and come up with your claims). If it can pass the rigor here, it can pass the rigor in the states and people will know it is a good product.”

She also stresses that her libido formula takes two to three weeks—not hours—to have an effect, a far-cry from the “crazy promises” she sees on bottles elsewhere.

Newcomers to any of the highly scrutinized categories would be wise to take a similar, prudent approach. As Schulman puts it, “Instead of making the strongest, boldest claim you think you can make, back down a little bit—maybe even farther than you want to. You want to really stay on the right side of the fence.”